support as this one does. It is costing millions of dollars to comply with the ridiculous delays from FDA, and the American people are being deprived of medicines and devices that should be approved much quicker. Some of them are just impossible to explain.

I hope that we can complete action this week.

I appreciate the efforts and the leadership of the Senator from Vermont.

Mr. HARKIN. If the leader will yield, I have a question.

So we are not having a cloture vote at 10 a.m. Was there a unanimous-consent agreement entered into that I missed before I came onto the floor?

Mr. LOTT. No. There was no unanimous-consent agreement.

Mr. HARKIN. Are we not voting at 10 o'clock?

Mr. LOTT. We have a Senator that is unavoidably detained that really is anxious to be present on that vote. We are trying to accommodate his schedule, as I know the Senator from Iowa would want us to do. We are working with the managers of both this bill and Interior appropriations and the interested Senators to see when we might have that vote. We would at some point try to enter into an agreement as to when it would be.

Mr. HARKIN. Are we going on the FDA bill?

Mr. LOTT. We will talk about it for a little while. But at 10 o'clock we will advise Members whether we are going to have a vote, or when we are deferring it to.

Mr. President, I yield the floor.

RESERVATION OF LEADER TIME

The PRESIDING OFFICER (Mr. HUTCHINSON). Under the previous order, leader time is reserved.

FOOD AND DRUG ADMINISTRATION MODERNIZATION AND ACCOUNTABILITY ACT OF 1997

The PRESIDING OFFICER. The Senate will now resume consideration of S. 830, with the time until 10 a.m. to be equally divided.

The clerk will report.

The assistant legislative clerk read as follows:

A bill (S. 830) to amend the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act to improve the regulation of food, drugs, devices, and biological products, and for other purposes.

The Senate resumed consideration of the bill.

Mr. JEFFORDS addressed the Chair.

The PRESIDING OFFICER. The Senator from Vermont is recognized.

MODIFIED COMMITTEE SUBSTITUTE AMENDMENT NO. 1130

Mr. JEFFORDS. Mr. President, I yield myself such time as I may consume.

Mr. President, we are here to discuss yet again the need for cloture on S. 830, the FDA Modernization and Accounting Act. We have already had 14 hours of floor debate on this measure and we have not yet discussed this amendment. This will be the second time that cloture has been voted on regarding this measure. The first vote was 89 to 5 to invoke cloture. The Senate has spoken. And, yet, we are here to repeat ourselves again and again.

My colleagues have already heard repeatedly from both sides of the aisle about the strong bipartisan commitment to crafting this measure, about the months of negotiations, deliberation and collaboration with the administration, the minority, and outside groups. Literally dozens of accommodations have been made and agreements reached. No one disputes that this is a good bill. No one should dispute that we have moved forward, or that we should move forward, with our debate on the remaining issues. Now we should move forward on that debate.

This measure accomplishes two very important objectives. First, it modernizes the way that the Food and Drug Administration accomplishes its mission. It streamlines the review and approval process for medical devices, pharmaceutical, and biological products. In so doing, it helps to ensure that the best and safest medical technology available in the world would be available to the American people. In so doing, it helps ensure that the best medical technology jobs will continue to be available for the American people.

Second, this measure authorizes the Prescription Drug User Fee Act—or PDUFA, as it is known. Everyone agrees that PDUFA has been immensely successful in helping FDA do its job better and more efficiently.

Mr. President, congressional authorization for PDUFA expires in 15 days. At the end of September this successful and innovative program will be at serious risk. It is the height of irony that a program like PDUFA that was designed to reduce delay at the FDA is now at risk of becoming bogged-down in a procedural delay on the Senate floor.

I would argue that the time for delay is over, and that the time for the Senate to do its work it was sent here to do is now.

Almost 50 amendments have been filed on this measure. And, frankly, virtually all of them are nongermane, or they have been worked out, or they can be worked out. A single provision remains that may require some extended debate, and we should move to its consideration and an up-or-down vote on it as soon as possible.

Last week we spent almost 15 hours talking about uniformity for cosmetics. We have an agreement on that provision, thanks to the efforts of Senator GREGG.

I say that we should move on. I say we complete this debate, and finish this measure, and let's vote.

Mr. President, I yield the floor.

Mr. KENNEDY addressed the Chair.

The PRESIDING OFFICER. The Senator from Massachusetts.

Mr. KENNEDY. Mr. President, with all due respect to my friend and colleague, the majority leader, the fact of the matter is by the votes that we had last week requiring that we have some opportunity to examine a very important provision—and that is the preemption of various States' ability to protect their public—we have seen a rather dramatic change in the language of the provision that will continue to permit the States to protect their public. That was very important for the protection of the American public. I know that there are some people around here who want to see the trains run on time. But some of us—not only those of us here but the National Governors' Conference, the public health organizations, the women's network organizations that deal with women's health issues—a wide range of consumers believe, quite deeply, that we are absolutely within our rights to make sure that this provision was offered and changed, and we did so. And, by doing so, the public health interest is preserved.

Now here we are on the floor of the U.S. Senate the morning after having seen the headlines from two national journals—yesterday in the Wall Street Journal, talking about a particular prescription drug called fen/phen, that had been moved through, rushed through the FDA. It has been linked to everything from brain damage in animals to primary pulmonary hypertension; a rare but fatal lung disease; millions of Americans tried the drugs to slim down; some 60 million people worldwide were estimated to have taken the drug; the straw that broke the camel's back was a heart valve problem which now has been widely recognized.

Here is an item in the Washington Post. Two diet drugs are pulled off the market. Why? Because the products were used for purposes for which the drug was not approved.

We are talking about an identical provision in this body with regard to medical devices—the use of the medical device for purposes for which it has not been approved.

We have seen the whole world being awakened to this particular health problem. Some of us are trying to making sure that we don't have headlines like this in 3 months, 4 months, or 6 months with regard to the medical device issue. That is what we are talking about.

Mr. President, I would just point out that there are about six little words that, if the majority would be willing to accept, would move us right ahead, and get us very short time agreements on the other elements.

Let me just point out. Mr. President, there are the two provisions with regard to medical devices—one they call class II—devices which represent about 5 percent of the devices. Those are the new devices.